CTSU BI-MONTHLY BROADCAST
November 08, 2005

The CTSU is distributing this bi-monthly broadcast summary to notify registered members of recent CTSU protocol activations and closures, protocol-specific addenda or memoranda issued by the Cooperative Groups, drug notices and safety reports, and general CTSU memoranda and notices. These documents will continue to be posted on the CTSU web sites in a timely manner. CTSU will continue to send out urgent broadcast messages, on an as-needed basis. CTSU will immediately notify sites that have submitted site registration materials for that particular protocol.

This broadcast will have a single link to our Registered Member Web Site. These documents can be found on the CTSU Registered Member Web Site: http://members.ctsu.org by clicking on the link for "Bi-monthly Broadcasts" just above the Protocol Updates on the right-hand side of the screen. This is a protected site; your username and password will be required to enter. If you are unsure of either or if you have any difficulty accessing the site, please contact us

at: CTSUWebmaster@westat.com or at 1-888-823-5923.

CTSU CANADIAN INVESTIGATORS SHOULD ALSO REFER TO THE ADDITIONAL CONTENT AT THE END OF THIS BROADCAST.

*** CTSU MEMORANDA ***

1. DO NOT LOSE ENROLLMENT PRIVILEGES: Over 500 institutions with active Group affiliations do not have an FWA on file in the RSS database. As of Jan. 1st, 2006 sites without an active FWA in RSS will have all site registration statuses set to pending. Please have the person responsible for regulatory matters at your institution check the RSS page on the CTSU web site and verify the FWA information. Instructions to submit updated FWA information to the CTSU Regulatory Office can also be found on the RSS page.

*** 'WHAT'S NEW' POSTINGS ***

1. The October 2005 edition of the E4402 newsletter is now available on the E4402 protocol page under Education and Promotion materials.

*** SUSPENSIONS and CLOSURES ***

1. E3201: PERMANENT CLOSURE
   Closure Date: 10/28/05
   Protocol Title: Intergroup Randomized Phase III Study of Postoperative Irinotecan, 5-Fluorouracil and Leucovorin versus Oxaliplatin, 5-Fluorouracil and Leucovorin versus 5-Fluorouracil and Leucovorin for Patients with Stage II or III Rectal Cancer Receiving Either Preoperative Radiation and 5-Fluorouracil or Postoperative Radiation and 5-Fluorouracil

*** PROTOCOL-SPECIFIC ADDENDA, REVISIONS, and MEMORANDA ***

1. E1Z03
   Memorandum: Revised Eligibility Checklist, Memorandum Date: 11/2/05

Protocol Title: Quality of Life Companion Study for JMA27 (NCIC-MA.27): A Randomized Phase III Trial of Exemestane Versus Anastrozole in Postmenopausal Women With Receptor Positive Primary Breast Cancer

2. E2603
   Memorandum: Revised Registration Worksheet, Memorandum Date: 11/2/05
   Protocol Title: A Double-Blind, Randomized, Placebo-Controlled Phase III Trial of Carboplatin, Paclitaxel, and BAY 43-9006 versus Carboplatin, Paclitaxel and Placebo in Patients with Unresectable Locally Advanced or Stage IV Melanoma

3. IBCSG-24-02, IBCSG-25-02, IBCSG-26-02
   STP Amendment 1 Overview (Oct 2005)

   Protocol Titles:
   IBCSG-24-02: A Phase III Trial Evaluating the Role of Ovarian Function Suppression and the Role of Exemestane as Adjuvant Therapies for Premenopausal Women with Endocrine Responsive Breast Cancer (SOFT)
   IBCSG-25-02: A Phase III Trial Evaluating the Role of Exemestane Plus GnRH Analogue as Adjuvant Therapy for Premenopausal Women with Endocrine Responsive Breast Cancer (TEXT)
   IBCSG-26-02: A Phase III Trial Evaluating the Role of Chemotherapy as Adjuvant Therapy for Premenopausal Women with Endocrine Responsive Breast Cancer Who Receive Endocrine Therapy (PERCHE)

4. N0147
   Memorandum: Omissions in Addendum 5, Memorandum Date: 11/07/05
   Protocol Title: A Randomized Phase III Trial of Oxaliplatin (OXAL) Plus 5-Fluorouracil (5-FU)/Leucovorin (CF) with or without Cetuximab (C225) after Curative Resection for Patients with Stage III Colon Cancer

5. NCIC CTG BR.19
   Memorandum: Reminder for BR.19 and MA.27 Data Submissions
   Memorandum Date: 11/8/05
   Protocol Title: A Phase III Prospective Randomized, Double-Blind, Placebo-Controlled Trial of the Epidermal Growth Factor Receptor Antagonist, ZD1839 (IRESSA) in Completely Resected Primary Stage IB, II and IIIA Non-Small Cell Lung Cancer

6. NCIC CTG MA.20
   Memorandum: Investigator Letter for use of Trastuzumab, Memorandum Date: 10/27/05
   Protocol Title: A Phase III Study of Regional Radiation Therapy in Early Breast Cancer

7. NCIC CTG MA.27
   Memorandum: Reminder for BR.19 and MA.27 Data Submissions
   Memorandum Date: 11/8/05
   Protocol Title: A Randomized Phase III Trial of Exemestane versus Anastrozole in Postmenopausal Women with Receptor Positive Primary Breast Cancer

8. RTOG 0232
   Amendment #2, Amendment Date: 10/27/05

Protocol Title: A Phase III Study Comparing Combined External Beam Radiation and Transperineal Interstitial Permanent Brachytherapy With Brachytherapy Alone for Selected Patients With Intermediate Risk Prostatic Carcinoma

9. RTOG 0421
   Forms Revision Notice, Memo Date: 11/1/05
   Protocol Title: A Phase III Trial for Locally Recurrent, Previously Irradiated Head and Neck Cancer: Concurrent Re-irradiation and Chemotherapy versus Chemotherapy Alone

10. S0012
    Memorandum: Clonal Hematopoiesis Collection Closed to New Patients
    Memorandum Date: 11/03/05
    Protocol Title: A Comparative Randomized Study of Standard Doxorubicin And Cyclophosphamide Followed by Weekly Paclitaxel Vs. Weekly Doxorubicin And Daily Oral Cyclophosphamide Plus G-CSF Followed by Weekly Paclitaxel As Neoadjuvant Therapy For Inflammatory And Locally Advanced Breast Cancer

11. S9925
    Amendment #12, Amendment Date: 11/01/05
    Protocol Title: Lung Cancer Specimen Repository Protocol, Ancillary

Please remember to obtain updated protocol-specific materials from the Web site and delete outdated versions.

***** ADDED / REVISED / REMOVED FORMS *****

The following form (#)'s have been revised.

1. E1Z03
   Eligibility Checklist, Version Date: 11/1/05

2. E2603
   Registration Worksheet/Eligibility Checklist, Version Date: 11/1/05

3. RTOG 0421
   HP Health Utility Measurement, Version Date: 11/1/05
   QOL Instructions for Investigators/RA's, Version Date: 11/1/05

4. RTOG 0232
   Eligibility Checklist, Version Date: 10/11/05

5. SWOG S9925
   Eligibility Checklist, Version Date: 10/18/05

Please remember to obtain updated protocol-specific materials from the Web site and delete outdated versions.

***** DRUG SAFETY REPORTS *****

These notices and reports are available on the "Protocols" Web page under the header "Drug Safety Notifications". Drug safety notifications should be submitted to your IRB/REB at time of

initial study registration (accompanied by the Investigator Brochure) and as additional reports are released via CTSU's Bi-monthly Broadcasts.

Group: ECOG

1. Protocol Number: E2100 (Closed), E3200 (Closed), E4599 (Closed), E5202
   Agent: Bevacizumab, Number of Reports: 1
   Cover Memo Date and AE Number
   - 11/02/05; Cover Memo; AE# 1034180, **NCI SAE Report** dated 09/15/05)

Group: ECOG

2. Protocol Number: E2603
   Agent: Bay 43-9003, Number of Reports: 1
   Cover Memo Date and AE Number
   - 11/02/05; Cover Memo; AE#
   - 200513609GDS, Initial
   - 200513476GDS, Initial
   - 200513476GDS, f/u# 1
   - 200512326BWH, Initial
   - 200512257BWH, Initial
   - 200512240BWH, Initial
   - 200512212BWH, Initial
   - 200512206BWH, Initial
   - 200512206BWH, f/u# 1
   - 200512204BWH, Initial
   - 200512204BWH, f/u# 1
   - 200512174BWH, Initial
   - 200512173BWH, Initial
   - 200512173BWH, f/u# 1
   - 200512144BWH, Initial
   - 200512108BWH, Initial
   - 200512108BWH, f/u# 1
   - 200512106BWH, Initial
   - 200512019BWH, f/u# 1
   - 200511995BWH, f/u# 1
   - 200511964BWH, f/u# 2
   - 200511951BWH, f/u# 1
   - 200511823BWH, f/u# 2
   - 200511634BWH, f/u# 1
   - 200511572BWH, f/u# 4
   - 200511572BWH, f/u# 3
   - 200511415BWH, f/u# 1
   - 200510972BVD, Initial
   - 200510938BVD, Initial
   - 200510927BVD, f/u# 1
   - 200510869BVD, f/u# 3
   - 200510790BVD, f/u# 1
   - 200510780BVD, f/u# 2
   - 200510767BVD, f/u# 2
   - 200510759BVD, f/u# 3
   - 200510707BVD, f/u# 1
   - 200510681BVD, f/u# 2

- 200510632BNE, f/u# 1
- 200510576BNE, f/u# 2
- 200510574BNE, f/u# 1
- 200510548BFR, f/u# 3
- 200510494BYL, Initial
- 200510494BYL, f/u# 1
- 200510327BVD, f/u# 4
- 200418433BWH, f/u# 4
- 200418433BWH, f/u# 3
- 200325935BWH, f/u# 8

Group: ECOG

3. Protocol Number: E4A03
   Agent: CC-5013, Number of Reports: 1
   Cover Memo Date and AE Number
   - 11/02/05; Cover Memo; AE# 1304132 (**NCI SAE Report** dated 09/26/05)

Group: NCCTG

4. Protocol Number: N0147
   Agent: Cetuximab, Number of Reports: 12
   Cover Memo Date and AE Number
   - 10/31/05; DDL # 178, ImClone 05-02-06472
   - 10/31/05; DDL # 177, ImClone 05-02-06154
   - 10/31/05; DDL # 176, ImClone 05-02-06437
   - 10/31/05; DDL # 175, ImClone 05-02-06334
   - 10/31/05; DDL # 174, ImClone 05-02-06413
   - 10/31/05; DDL # 173, ImClone 05-02-06322
   - 10/31/05; DDL # 173(1), ImClone 05-02-06322
   - 10/31/05; DDL # 172, ImClone 05-02-06292
   - 10/31/05; DDL # 172(1), ImClone 05-02-06292
   - 10/31/05; DDL # 170(1), ImClone 05-02-06233
   - 10/31/05; DDL # 169(1), ImClone 05-02-06261
   - 10/31/05; DDL # 166(2), ImClone 05-02-06115

Group: NSABP

5. Protocol Number: NSABP-B-38
   Agent: Gemcitabine, Number of Reports: 5
   Cover Memo Date and AE Number
   - 10/25/05; Cover Memo
   - 10/12/05; Safety Update #47
   - 10/12/05; Safety Update #46
   - 10/05/05; Safety Update #45
   - 09/28/05; Safety Update #44

Group: NSABP

6. Protocol Number: NSABP-C-08
   Agent: Bebacizumab, Number of Reports: 2
   Cover Memo Date and AE Number
   - 10/25/05; Cover Memo
   - 09/15/05; AE#: 1034180, Safety Update #16

Group: SWOG

7. Protocol Number: S0200 (Closed)
   Agent: Pegylated Liposomal Doxorubicin, Number of Reports: 3
   Cover Memo Date and AE Number
   - 11/01/05; Cover Memo
   - 09/30/05; AE#: 20050905722(3)
   - 09/29/05; AE#: 20050905722(0)

Group: SWOG

8. Protocol Number: S0205
   Agent: Cetuximab, Number of Reports: 8
   Cover Memo Date and AE Number
   - 11/01/05; Cover Memo
   - 10/18/05; DDL # 178, ImClone 05-02-06472
   - 10/17/05; DDL # 173(1), ImClone 05-02-06322
   - 10/14/05; DDL # 166(2), ImClone 05-02-06115
   - 10/13/05; DDL # 172(1), ImClone 05-02-06292
   - 10/12/05; DDL # 177, ImClone 05-02-06154
   - 10/12/05; DDL # 176, ImClone 05-02-06437
   - 10/12/05; DDL # 175, ImClone 05-02-06334

*** INFORMATION FOR CTSU CANADIAN INVESTIGATORS ***

Canadian institutions are responsible for reviewing study-specific drug safety reports released by both the lead Group and by the Canadian study sponsor. These reports are located in two separate areas of the CTSU Member Web site:

Notices distributed by the lead Group are posted on the CTSU Drug Safety Notifications Web page and are listed under the Drug Safety Reports section of this broadcast.

Notices distributed by the Canadian study sponsor in compliance with Health Canada regulations are posted on the protocol-specific Canadian Web page and are listed below.

1. CALGB-90206, E2100
   Bevacizumab IND Safety Report, AE#: 1034180 (09/15/05)

2. E4201
   Gemzar, Report#: US_0509121492 (09/21/05)

3. N0147, S0205
   Cetuximab Safety Update DDL181_05-02-06321 (10/31/05)

4. NSABP B-35
   Health Canada Approval of Amendment #2
   Protocol Title: A Clinical Trial Comparing Anastrozole with Tamoxifen in Postmenopausal Patients with Ductal Carcinoma in Situ (DCIS) Undergoing Lumpectomy with Radiation Therapy